



## UNITED STATES DEPARTMENT OF COMMERCE

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EXAMINER

EISENSCHENK, F.

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18N1/1214

ART UNIT

PAPER NUMBER

5

1816

DATE MAILED:

12/14/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on \_\_\_\_\_  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

## Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1.  Notice of References Cited by Examiner, PTO-892.  
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.  
3.  Notice of Art Cited by Applicant, PTO-1449.  
4.  Notice of Informal Patent Application, PTO-152.  
5.  Information on How to Effect Drawing Changes, PTO-1474.  
6.

## Part II SUMMARY OF ACTION

1.  Claims 1-16 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 1-16 are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).

12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

## EXAMINER'S ACTION

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15. The location of this application has changed. All future correspondence regarding this application should be sent to the Examiner's attention with art unit designation 1816. Current fax and telephone contact numbers may be found at the end of this Office Action.
16. Applicant is reminded that the photographs are not acceptable until a petition is granted, see box 2 of the PTO 948 form, attached to Paper No. 5.
17. Claims 2-7, and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A) Claims 2-7 and 14 are rejected as being indefinite because of the phrases "substantially reduce", "substantially inhibit", or "substantially interfere". These phrases do not appear to have been defined in the specification and it is unclear what these phrases mean in terms of the interference, inhibition, or reduction required. Namely, is a 5% reduction considered to be substantial or is 50% considered to be substantial.
18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

  - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
19. Claims 1-10, 14, and 15-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sindelar et al. (U.S. Patent 5, 173,499). The patent teaches methods for the treatment of established joint inflammation comprising the administration of an effective amount of a C5 blocker. The invention of '499 is taught to be useful in the treatment of inflammatory disorders, such as rheumatoid arthritis, through the selective inhibition of C5 (see Table 3, claims 3-13, columns 5-10, and columns 22-23). Rheumatoid arthritis is considered an established joint inflammation, i.e. an inflammatory disease (see specification, page 11). By inhibiting the cleavage of C5, the inhibitors of '499 substantially inhibit the cell-lysing ability of complement in the serum of a patient. The method of the '499 patent would also substantially reduce the

level of C5b-9 in the plasma of a patient because the compounds of the '499 patent inhibit the cleavage and activation of C5 into C5a and C5b. According to Figures 2-3 of the '499 patent, the compounds of the patent are capable of reducing the cell lysing ability of complement by at least 10% as well as the amount of C5a by at least 10%. The blockers of the '499 patent also do not appear to substantially interfere with the cleavage of C3 (see Figure 2). The compounds of the '499 patent are considered to be within the scope the recited "C5 blocker" (see specification, pages 19 and 25-26). The '499 patent also teaches pharmaceutical compositions comprising the compounds taught therein. The article of manufacture claims are considered anticipated by the teachings of the patent at column 23, lines 60-68. The '499 patent teaches pharmaceutical compositions comprising the C5 blockers of the reference. Claims 15-16 claim an article of manufacture comprising packaging material and a pharmaceutical agent, wherein the pharmaceutical agent is a C5 blocker and the packaging comprises printed material, subject matter which does not serve to distinguish the claimed compounds from the prior art compounds. The Court of Customs and Patent Appeals has stated that known compositions do not undergo a metamorphosis to a new composition by labelling a container to show new an intended use for an old product. The container would still contain the old product. See In re Pearson, 494 F.2d 1399, 1403 (CCPA 1974).

20. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of

assignment to the same person.

21. Claims 11-13 are rejected under 35 U.S.C. § 103 as being unpatentable over Sindelar et al. ('499), as applied above, in view of Auda et al. (Rheumatol. Int.). Claims 11-13 are drawn to methods for the treatment of established joint inflammation comprising the administration of an effective amount of a C5 blocker and further comprising the determination of the C5a and/or C5b level through ELISA assays or chemotactic assays to evaluate the patient's response to the treatment protocol. The teachings of the Sindelar reference have been discussed supra. The reference differs from the claimed invention in that the monitoring of C5a and or C5b levels following the administration of the C5 blocker to monitor patient response to treatment is not taught. Auda et al. teach the measurement of complement activation products in patients suffering chronic rheumatic diseases and that such measurements provide additional information which allows for the prediction of patient clinical status (see Discussion). Auden further teach that the monitoring of C5b-9 levels in patients may provide for a more sensitive indicator or patient status than other indicators of disease status (Discussion, page 188, last 2 paragraphs). Such an assay would allow for the measurement of C5b levels within the C5b-9 complexes.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the teachings of Auda et al. to determine the levels of C5a and/or C5b in the fluid samples of patients being treated according to the teachings of Sindelar in order to determine the clinical status of the patients so treated. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

23. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).
24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. The examiner can normally be reached Monday through Thursday from 6:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Margaret M. Parr can be reached on (703) 308-2454. The fax phone number for Group 180 is (703) 305-3014 or (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

December 12, 1995  
Christopher Eisenschenk, Ph.D.  
Patent Examiner  
Group 1800

*CEisenschenk*

FRANK C. EISENSCHENK  
PATENT EXAMINER  
GROUP 1800